K003577

JAN 2 9 2001

Attachment 3

510(k) SUMMARY
STERIS® DeepSite™ Fiber Optic Surgical Light

Submitter Information:

STERIS Corporation
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Raymond Ursick
VP Regulatory Affairs & Quality Systems

Date Summary Prepared: November 16, 2000

Name of the device: STERIS DeepSite Fiber Optic Surgical Light

Common or usual name of the device: Light, Surgical, Fiber Optic

Classification name of the device: Surgical Lamp

Predicate Device: Cuda Surgical Light with Cermax300 Light source

Device Description: The STERIS DeepSite Fiber Optic Light is a variable pattern, variable intensity fiber optic surgical light designed to provide visible illumination of the surgical field or the patient. The DeepSite consists of a center-mounted suspension, a flexible "gooseneck" supported lighthead for ease of positioning, and an electronic control. The STERIS DeepSite Fiber Optic Surgical Light is designed as a task light for surgical use. The DeepSite has a sterile disposable sheath for positioning of the light as needed and maintenance of the sterile field during surgical procedures. The sterile sheath is latex free and is made of approved medical grade material to specifically accommodate the DeepSite. The STERIS DeepSite Fiber Optic Surgical Light is designed to comply with IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). The device carries the ETL (to UL 2601-1) and cETL (to CAN/CSA C22.2 No. 601.1-M90) markings.

The STERIS light is designed to be a substitute or a replacement for headlamps. The technology used in the device is the same technology currently used in other headlamps and light sources with similar performance characteristics which have been previously cleared by the FDA.

Intended Use: The STERIS DeepSite Fiber Optic Light is a variable pattern, variable intensity fiber optic surgical light designed to provide visible illumination of the surgical field or the patient. The STERIS DeepSite Fiber Optic Surgical Light is designed as a task light for surgical use. The device is intended to be used by surgeons and other medical care practitioners in a surgical setting.

Device Comparison Chart:

Specification	The STERIS DeepSite Fiber Optic Surgical Light	The Cuda Surgical Light with Cermax300 Lightsource
Electrical	120 volts, 50/60 Hz	120 volts, 50/60 Hz
Lamp	15 Volt, 300 Watt Xenon Arc	15 Volt, 300 Watt Xenon Arc
Fiber Optic Cable	1/4" diameter plastic core with a poly-propylene insulating sleeve	1/4" diameter glass bundle cable
Illumination (lumens)	approximately 700 lumens at the end of an 18 foot long fiber optic cable	800 lumens at exit end of 5mm dia x 7 1/2 ft long fiber optic bundle
Beam Size (Diameter)	Approximately 2 to 6 inches in diameter, variable at a recommended working distance of 15 to 22 inches	20 mm (0.8 in) to 100 mm (4 in) in diameter, variable
Color Temperature (°K)	6000° Kelvin	6000° Kelvin
UV Output (watts/cm^2)	.06 watts/cm^2	Not Available
Lamp Cooling Method	Forced air with a heat sink	Forced air with a heat sink
Disposable Sterile Sheath	Yes	Yes
Bio-compatibility	N/A, no patient contact	N/A, no patient contact

Substantial Equivalence

The STERIS DeepSite Fiber Optic Surgical Light is substantially equivalent to The CUDA Surgical Light in function and intended use. Similarities and differences are listed below:

Similarities with the CUDA Surgical Light

- ♦Has the same intended use
- ♦Incorporates similar lighting technology
- ♦Utilizes a flexible "gooseneck" for ease of positioning
- ♦Uses the same operating principle

Differences with the CUDA Surgical Light

- ♦The STERIS DeepSite Fiber Optic Surgical Light is ceiling mounted as opposed to being wall mounted or attached to a stand.
- ♦The controls for the STERIS DeepSite Fiber Optic Surgical Light are located in a separate control unit as opposed to being located on the illuminator.
- ♦The STERIS DeepSite Fiber Optic Surgical Light is designed to operate with a dedicated light source.

The STERIS DeepSite Fiber Optic Surgical Light is substantially equivalent to the CUDA Surgical Light predicate device. The minor differences described above between the STERIS DeepSite Fiber Optic Surgical Light's configuration and that of the predicate CUDA Surgical Light do not raise any issues of safety or effectiveness. The intended use, basic technology, and performance characteristics of the systems are the same. The device does not contact the patient, so bio-compatibility is not a concern.

Discussion of non-clinical tests.

The STERIS DeepSite Fiber Optic Surgical Light utilizes existing fiber optic technology and a flexible "gooseneck" to position the light to deliver illumination to the operative site. The ability of the STERIS DeepSite Fiber Optic Surgical Light to meet the established performance specifications has been established through non-clinical tests. These non-clinical tests include (but were not limited to) evaluations of optical characteristics (illuminance, pattern size, radiant energy), mechanical characteristics (load carrying capacity, ease of positioning, drift-free performance), electrical characteristics (software, safety, electromagnetic compatibility). Dimensional specifications and the ergonomics of patient-user interface have also been examined to ensure the device meets human factors considerations.

Discussion of clinical tests.

For the STERIS DeepSite Fiber Optic Surgical Light clinical testing was not performed, bench testing is sufficient to prove the safety and efficacy of the device.

Conclusions drawn from the non-clinical and clinical tests.

Based on the non-clinical testing of the STERIS DeepSite Fiber Optic Surgical Light, there are no new questions of safety or efficacy that have been raised. The STERIS DeepSite Fiber Optic Surgical Light meets it's intended use of safely and effectively providing visible illumination of the surgical field or the patient. For safe and effective use of the STERIS DeepSite Fiber Optic Surgical Light it is essential to follow the recommendations contained in the manuals provided with the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2001

Mr. Robert H. McCall
Senior Regulatory Compliance Specialist
STERIS Corporation
2720 Gunter Park Drive East
P.O. Box 3509
Montgomery, Alabama 36109

Re: K003577
Trade Name: STERIS® DeepSite™ Fiber Optic Surgical Light
Regulatory Class: II
Product Code: FST
Dated: November 16, 2000
Received: November 20, 2000

Dear Mr. McCall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note; this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known)

Device Name STERIS® DeepSite™ Fiber Optic Surgical Light

Indications for Use

The STERIS® DeepSite™ Fiber Optic Surgical Light is a variable pattern, variable intensity fiber optic surgical light designed to provide visible illumination of the surgical field or the patient. The DeepSite consists of a center-mounted suspension, a flexible "gooseneck" supported lighthead for ease of positioning, and an electronic control. The STERIS DeepSite Fiber Optic Surgical Light is designed as a task light for surgical use.

The device is intended to be used by surgeons and other medical care practitioners in a surgical setting.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003577

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)